# biotechne

# OEM Services MolecularDx Controls

Asuragen, a Bio-Techne brand, has been custom manufacturing robust, reliable molecular controls for the diagnostic industry for more than 20 years.

Our Armored RNA<sup>®</sup>, Armored RNA Quant<sup>®</sup>, Armored DNA Quant<sup>™</sup>, plasmid DNA (circular and linearized), and *in vitro* transcribed RNA provide unique, target-specific solutions to meet all your molecular quality control needs.

#### **Our OEM services include**

- ISO 13485 certified quality system
- Evaluation, Development, and cGMP grade product
- Customer-defined target sequences
- Validated equipment, environmental monitoring
- Custom formulation, filling, and labeling
- Standardized supply agreements
- Scalable E. coli cell bank production



Optimally designed to ensure the dependability and accuracy of your molecular test:

**Stable:** Armored technology encapsulates molecular controls in a protein coat making them nuclease resistant in most sample matrices.

**Non-infectious:** Synthetic controls are safe for worldwide distribution and are easy to export/import.

**Customizable:** *In vitro* synthesis can be tailored to create specific controls for single targets or multiplexed panels.

### Assay Development through Global Commercialization

Delivering custom design, reliable service, and seamless integration for molecular diagnostic manufacturers



Evaluate Needs



Customize Solutions



Select Products



Secure Supply Agreement

cGMP Manufacture

# Why Partner with Us?

Combined expertise in RNA and DNA with in-depth knowledge of regulated manufacturing operations results in high quality, consistent products

### **Scientific Expertise**

Our scientists can clone and characterize virtually any customer-defined in silico sequence to deliver targeted nucleic acid or ensure compatibility with Armoring technology.

### **Quality Systems**

Our ISO 13485 certified quality system is subject to continuous assessment by regulatory authorities, assessing organizations, external partners, and internal quality assurance personnel to ensure timely review of records and compliance with applicable standards.

### Asuragen provides custom development and manufacturing services

Supply Continuity

Long-term cell banking of E. coli host in our validated cryopreservation system and use of multiple qualified suppliers minimizes supply chain disruption.



# Simplicity

Starting with a customer-derived in silico target sequence or plasmid stock, Asuragen is a single source for all development and manufacturing activities to meet customer specifications and requirements.



**Custom Manufacturing Capabilities** 

labeling needs.

Our cGMP manufacturing facility can accommodate a wide range of specifications as a flexible approach to

target different sequence, concentration, filling, and

## Scalability

Manufacturing of all custom products can be scaled to any volume, copy number concentration, or quantity to meet your individual needs.

Contact Us | aus.armored@bio-techne.com



Bio-Techne® R&D Systems<sup>™</sup> Novus Biologicals<sup>™</sup> Tocris Bioscience<sup>™</sup> ProteinSimple<sup>™</sup> ACD<sup>™</sup> Asuragen® Trademarks and registered trademarks are the property of their respective owners.

\*For Research Use Only. Not For Use in Diagnostic Procedures.

4000-044 Rev B 10/22 STRY0257551\_ASU\_FL\_OEM-Serv-MolDx\_JA